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09/242,772	06/25/1999	WILLEM JAN MARIE VAN DE VEN	702-990278	1485

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EXAMINER

KIM, YOUNG J

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/242,772

Applicant(s)

VAN DE VEN ET AL.

Examiner

Young J. Kim

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 53-58 is/are pending in the application.
- 4a) Of the above claim(s) 58 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 53 is/are allowed.
- 6) ☒ Claim(s) 54-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 February 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

The Examiner of record has been changed. All further correspondence regarding this application should be directed to Examiner Young J. Kim whose Group Art Unit is 1637.

#### *Preliminary Remark*

Newly submitted claim 58 is directed to an invention that is independent or distinct from the invention originally examined for the following reasons:

Applicants' After-Final amendment received on June 29, 2004, submitting claim 58 subsequent to the Final Rejection mailed on February 25, 2004 had been denied in the Advisory Action mailed on July 30, 2004, as containing claim that was not examined previously.

Claim 58 was introduced in the following RCE received on August 27, 2004 and examined in the Non-Final rejection mailed on November 19, 2004.

MPEP 706.07(h), in discussing RCE practice, discloses the following:

“Applicants cannot file an RCE to obtain continued examination on the basis of claims that are independent and distinct from the claims previously claimed and examined as a matter of right (i.e., applicant cannot switch inventions). See 37 CFR 1.145. Any newly submitted claims that are directed to an invention that is independent and distinct from the invention previously claimed will be withdrawn from consideration and not entered.”

It is determined that claim 58 is drawn to subject matter which is independent and distinct and which was not examined in the previous prosecution history (prior to the submission of RCE).

Claim 58 is drawn to an anti-sense nucleic acid molecule which inhibits the expression of the nucleic acid previously examined. The examination issues surrounding an anti-sense nucleic acid is not coextensive with the examination issues surrounding a nucleic acid whose patentability is based on different criteria (i.e., in its ability to inhibit expression).

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Hence, as Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 58 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 53-57 are under prosecution therefore.

### ***Claim Interpretation***

The interpretation regarding claim 53 is as follows:

Claim 53 recites the phrase, “[a]n isolated nucleic acid sequence *consisting of* 7313 base pairs as provided in SEQ ID NO: 116, *with an open reading* frame of 1500 base pairs starting with the ATG at position 481-483 *as provided in SEQ ID NO: 116.*” It appears that all of the recited limitations reads only on “an isolated nucleic acid consisting of SEQ ID NO: 116,” and could be written simpler by recitation of the phrase, “an isolated nucleic acid sequence consisting of SEQ ID NO: 116.”

This interpretation is assumed for prosecution, therefore.

### ***Specification***

The amendment to the specification received on August 7, 2003, removing a hyperlink, is acknowledged. The instant specification, however, contains an additional active hyperlink on page 21, lines 33-34.

While information on web-address is accessible, the embedded hyperlinks and/or other forms of browser-executable code are impermissible and require deletion. The attempt to incorporate subject matter into the patent application by reference to a hyperlink and/or other

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forms of browser-executable code is considered to be an improper incorporation by reference.

See MPEP 608.01(p), paragraph I regarding incorporation by reference.

If the subject matter which is improperly incorporated by reference is directed to nonessential material (illustrating the state of the art), the deletion will probably not be considered as new matter. However, if the subject matter which is improperly incorporated by reference is directed to essential material, applicant will be required to amend the specification to include the subject matter incorporated. The amendment must be accompanied by an affidavit or declaration executed by the applicant stating that the amendatory material consists of the same material incorporated by reference.

#### *Objection – Specification*

The specification is objected to for containing unclear description of the invention.

On page 43, beginning at line 37, the instant specification states that in tumors CG368, CG682, CG752, and T9587, PCR products of 509 bp (Figure 6A, PCR product A) and 614 bp (Figure 6A, PCR product B) were generated (finishing at page 44, line 1).

The specification then further describes the two PCR products as follows:

“whereas in tumors CG644 and CG753, only the PCR product of 509 bp was found....The PCR product of 605 bp contains an extra 105 bp, which corresponds to the alternatively spliced exon 2 of PLAG1.” (emphasis added, underlined original).

While PCR products A and B are initially described as being 509 bp and 614 bp, respectively, the subsequent description recites that “[t]he PCR product of 605 bp” does not have any antecedent basis, since PCR product B was described as being 614 bp, and not 605 bp.

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For the purpose of examination, it is assumed that the PCR products comprise 509 bp and 614 bp.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 55-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 56 is indefinite for reciting the phrase, “[a]n isolated nucleic acid sequence according to claim 55, *containing 509 base pairs corresponding to exon 1 of CTNNB1* fused to exons 3 and 5 of PLAG1,” because it is unclear whether the isolated nucleic acid sequence containing exon 1 of CTNNB1 fused to exons 3 to 5 of PLAG1 consists of 509 base pairs in length; or the isolated nucleic acid sequence contains 509 base pairs from exon 1 of CTNNB1 that is fused to exons 3 to 5 of PLAG1.

For the purpose of prosecution, the former interpretation is assumed.

Claim 57 is indefinite for analogous reasons as discussed above.

Claims 55-57 are indefinite because claims 54-57 refer to claim 54 as, “[a]n *isolated nucleic acid sequence*,” when in fact, claim 54 is drawn to an isolated *hybrid* nucleic acid sequence. Therefore, claim do not have proper antecedent basis for this limitation. Additionally, claim 54 is drawn to an isolated hybrid nucleic acid sequence which is formed by *fusing* of an isolated nucleic acid and a translocation partner of PLAG1, further rendering the claims

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confusing as to which of the nucleic acids the above phrase, “an *isolated nucleic acid sequence*,” is referring to.

For the purpose of prosecution, the phrase has been assumed to mean, “an isolated hybrid nucleic acid sequence.”

Claim 54 is indefinite for reciting the phrase, “[a]n isolated hybrid nucleic acid sequence consisting of a fragment of the nucleic acid ... fused to a *nucleic acid sequence comprised of a translocation partner of PLAG1*,” because it is unclear what is meant by a nucleic acid “comprised” of a translocation partner of PLAG1 – is it a fragment of a nucleic acid encoding the translocation partner; or is it a nucleic acid encoding a translocation partner; or is it a nucleic acid embedded in a nucleic acid encoding a translocation partner of PLAG1, etc.?

For the purpose of prosecution the nucleic acid sequence is interpreted to be a fragment of a nucleic acid encoding a translocation partner of PLAG1.

#### *Rejection - Withdrawn*

The New Matter rejection of claim 56 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, made in the Office Action mailed on November 19, 2004 is withdrawn in view of the careful reconsideration of the instant application.

The scope of enablement rejection of claims 56 and 57 under 35 U.S.C. 112, first paragraph, made in the Office Action mailed on November 19, 2004 is withdrawn in view of the careful reconsideration of the application. Specifically, the previous examiner included the dependent claims which were identified as enabling embodiments (claims 56 and 57), and therefore, the rejection is withdrawn.

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*Rejection – New Grounds*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 57 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter Rejection.

Preliminarily, the Examiner of record notes that the previous rejection made by the previous Examiner (in the Office Action mailed on November 19, 2004) appears to be in error.

Based on the interpretation of the description found on pages 43-44 of the instant specification, the application as filed provides proper description for a nucleic acid consisting of 614 base pairs and not 605 base pairs (as previous examiner contended).

According to pages 43 and 44 of the instant specification, two PCR products were found in tumor samples, identified as PCR product A and PCR product B. PCR product A is described as being 509 base pairs in length, wherein said PCR product is a hybrid transcript containing exon 1 of CTNNB1 and exons 3 to 5 of PLAG1 (page 44, lines 3-5). PCR product B is initially described as being 614 base pairs in length (page 44, line 1). And this PCR product is further described as follows:

“The PCR product of 605 bp contains an extra 105 bp, which corresponds to the alternatively spliced exon 2 of PLAG1..” (page 44, lines 5-7).



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When read in context, it appears that the “extra 105 bp” is described in light of PCR Product A which contains 509 base pairs. Hence, 105 “extra” base pairs from 509 base pairs of PCR product A, would result in 614 base pairs of PCR Product B.

The claim as amended, however, is drawn to nucleic acid which is not described in the specification as originally filed nor contemplated.

Deletion of new matter is required.

*Rejection – Maintained*

The New Matter rejection of claims 54 and 55 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, made in the Office Action mailed on November 19, 2004 is maintained for the reasons of record.

Applicants’ arguments presented in the Amendment received on April 11, 2005 have been fully considered but they are not found persuasive for the following reasons.

Applicants’ arguments are addressed in the same order they were presented.

Applicants contend that claim 54 has been amended to recite a fragment of nucleic acid sequence according to claim 53, fused to a nucleic acid sequence comprised of a translocation partner of PLAG1, wherein support for this limitation can be found on page 2, lines 37-38 and page 10, line 29.

Claim 54 is drawn to an isolated hybrid nucleic acid sequence consisting of any fragment of SEQ ID NO: 116 (including a single nucleotide therefrom) fused to any translocation partner of PLAG1.

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It is maintained that the application as originally filed (in claims, specification, and/or drawings) had not contemplated the broad class of hybrid nucleic acid.

With regard to page 2, lines 37-38, the instant specification disclose that “CTNNB1 gene was identified as the fusion partner gene of PLAG1,” thus does not provide support for a hybrid nucleic acid consisting of any fragment of SEQ ID NO: 116 fused to any translocation partner. The specification does not contain an explicit definition so as to exclude translocation partners other than CTNNB1.

With regard to page 10, the instant specification describes the invention drawn to the “derivatives of PLAG gene” and not PLAG1, nor a hybrid nucleic acid consisting of any fragment of SEQ ID NO: 116 fused to any translocation partner.

With regard to claim 55, while the hybrid nucleic acid is further limited as that which consists of a fragment of SEQ ID NO: 116 fused to a nucleic acid comprised of CTNNB1, the claim continues to embrace a hybrid nucleic acid consisting of any fragment of SEQ ID NO: 116 fused to nucleic acid comprised of CTNNB1, which does not find proper support under 35 U.S.C. 112, first paragraph.

Rejection is maintained therefore.

The rejection of claims 54 and 55 under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement, made in the Office Action mailed on November 19, 2004 is maintained for the reasons of record.

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Applicants' arguments presented in the Amendment received on April 11, 2005 (including Supplemental arguments) have been fully considered but they are not found persuasive for the following reasons.

Applicants contend that the specification states that CTNNB1 is a translocation partner of PLAG1. Applicants continue that the specification provides a hybrid nucleic acid sequence consisting of exon 1 of CTNNB1 fused to exon 3 to 5 of PLAG1, and exon 1 of CTNNB1 fused to exons 2 to 5 of PLAG1.

Applicants are reminded that claim 54 is not limited to the translocation partner of CTNNB1, but rather any translocation partner.

One skilled in the art regarding translocation of genes, would readily recognize that there are more than a single species of translocation partner for PLAG1.

This is evidenced by Voz et al. (Cancer Research, 2000, vol. 60, page 106-113). The artisans disclose that activation of PLAG1 gene on chromosome 8q12 is the most frequent gain-of-function mutation found in pleomorphic adenomas of the salivary glands, which mainly results from recurrent chromosomal translocation that lead to promoter substitution between PLAG1, a gene mainly expressed in fetal tissue, and more broadly expressed genes." (page 106, 1<sup>st</sup> column, *Introduction*).

Artisans continue to state, "[t]he three translocation partners characterized thus far are the  $\beta$ -catenin [also known as CTNNB1] gene on 3p21 found in most common translocation...the leukemia inhibitory factor receptor gene on 5p13...and the elongation factor *SII* gene." (page 106, 1<sup>st</sup> column, *Introduction*).

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Clearly, the instant application as filed did not have a reasonable number of species so as to demonstrate possession of a genus of hybrid nucleic acid consisting of fragment of PLAG1 and its wide diversity of translocation partners.

With regard to claim 55, while the hybrid nucleic acid is further limited to that which is fused to a nucleic acid sequence comprised of a translocation partner of PLAG1, wherein the translocation partner is CTNNB1, the claim still reads on a plurality of species of hybrid nucleic acids formed by the fusion of any fragment of SEQ ID NO: 116 and any region of CTNNB1.

The instant specification discloses 3 species – PCR product A and B (pages 43-44); and the PCR product of 130 base pairs, described as corresponding to “a fusion transcript consisting of exon 1 of PLAG1 and exons 2 to 16 of CTNNB1.

A reasonable number of species had not been disclosed for one skilled in the art to recognize that Applicants were in possession of the genus.

Rejection is maintained therefore.

The rejection of claims 54 and 55 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated hybrid nucleic acid sequence consisting of exon 1 of CTNNB1 fused to exons 3 to 5 of PLAG1, wherein said nucleic acid sequence is 509 base pairs; and an isolated hybrid nucleic acid sequence consisting of exon 1 of CTNNB1 fused to exons 2 to 5 of PLAG1, wherein said nucleic acid sequence is 614 base pairs, does not reasonably provide enablement for an isolated hybrid nucleic acid sequence consisting of any fragment of nucleic acid sequence fused to a nucleic acid sequence comprised of any translocation partner of PLAG1 (claim 54), or said translocation partner being CTNNB1. The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, made in the Office Action mailed on November 19, 2004 is maintained for the reasons of record.

Applicants' arguments presented in the Amendment received on April 11, 2005 have been fully considered but they are not found persuasive.

Applicants' arguments are addressed in the same order they were presented.

The enablement criteria under 35 U.S.C. 112, first paragraph is clear that the specification shall contain description so as to, "enable any person skilled in the art" to "make and use," the invention.

Applicants' contend that CTNBB1 is a translocation partner of PLAG1 (page 10, bottom paragraph, Response). However, it is clear that CTNBB1 is only a translocation partner of PLAG1.

In so far as claim 54 is concerned, as already discussed above, one skilled in the art would clearly recognize that the instant specification does not have reasonable number of species so as to enable a skilled artisan to make an isolated hybrid nucleic acid consisting of any fragment from SEQ ID NO: 1 fused to nucleic acid sequence comprised of any translocation partner (not limited to CTNBB1) which, "allows the diagnosis of a cell containing said hybrid nucleic acid sequence as a tumor cell."

The instant specification disclose 3 species of hybrid nucleic acids that are specific in structure, wherein the translocation partner is limited to CTNBB1. Thus, a skilled artisan to not only make but to use the genus of hybrid nucleic acid consisting of any fragment of SEQ ID NO:

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116 fused to any nucleic acid comprised of translocation partner of PLAG1 would require undue amount of experimentation.

Additionally, with regard to claim 55 drawn to an isolated hybrid nucleic acid consisting of any fragment of SEQ ID NO: 116 fused to a nucleic acid comprised of a translocation partner of PLAG1, wherein said translocation partner is CTNNB, the subgenus is not represented by a reasonable number of species as the instant specification discloses only three species of the hybrid nucleic acids.

The instant specification, beginning at page 43, bottom paragraph to page 44, states that PCR product of 509 base pairs; 614 base pairs; and 130 base pairs have been identified, two of which contain exon 1 of CTNNB1 fused to different exons of PLAG1 (page 44, lines 5-9), and one of which contains exons 2 to 16 fused exon 1 of PLAG1 (page 44, line 14).

It is determined that three species of fusion nucleic acid sequences (or hybrid nucleic acid), wherein the fusion is highly divergent, is not a representative number of species to enable a skilled artisan to not only make a use a genus of hybrid nucleic acids consisting of at least a fragment from any region of SEQ ID NO: 116 fused to any region of a nucleic acid comprised of CTNNB1 protein.

The instant specification does not give any guidance other than the structures of the three identified species so as to guide a skilled artisan to make and use the claimed invention commensurate in scope without undue experimentation.

Rejection is maintained therefore.

***Claim Rejections - 35 USC § 102***

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The rejection of claims 54 and 55 under 35 U.S.C. 102(b) as being anticipated by Nollet et al. (Genomics, March 1996, vol. 32, pages 413-424) made in the Office Action mailed on November 19, 2004 is withdrawn in view of the arguments presented in the Amendment received on April 11, 2005.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 54 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Nollet et al. (Genomics, March 1996, vol. 32, pages 413-424) as evidenced by Takayama et al., (American Journal of Pathology, 1996, vol. 1, pages 39-46).

The teachings of Nollet et al. have already been previously discussed. Specifically, Nollet et al. disclose nucleic acid encoding the protein CTNNB1.

Claim 54 is drawn to an isolated hybrid nucleic acid sequence consisting of *a fragment* of the nucleic acid sequence from SEQ ID NO: 116 fused to a nucleic acid sequence comprised of any translocation partner of PLAG1, wherein claim 55 further defines this translocation partner as being CTNNB1.

Structurally, such nucleic acid would embrace be any segment of sequence from CTNNB1 with at least one nucleotide from SEQ ID NO: 116. A nucleic acid sequence encoding CTNNB1 would necessarily anticipate such a nucleic acid.

With regard to Applicants' remark regarding the limitation defined by the phrase, "wherein the presence of said hybrid nucleic acid sequence allows the diagnosis of a cell

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containing said hybrid nucleic acid sequence as a tumor cell, Takayama et al. disclose that down-regulation of beta-catenin is associated with malignant transformation of a cell (i.e., cancer), evidencing that the nucleic acid of Nollet et al. allows diagnosis of tumor.

Therefore, the invention as claimed is anticipated by Nollet et al.

### ***Conclusion***

Claim 53 is free of prior art as the prior does not disclose a nucleic acid *consisting of* SEQ ID NO: 116.

### ***Inquiries***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m. The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

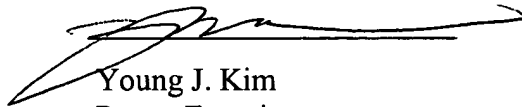
If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a



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general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Young J. Kim  
Patent Examiner  
Art Unit 1637  
6/15/2005

**YOUNG J. KIM  
PATENT EXAMINER**

yjk